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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,439	06/28/2007	Bradley Koepfel	2G02.1-191	5110
23506 7590 03/07/2008 GARDNER GROFF GREENWALD & VILLANUEVA, PC 2018 POWERS FERRY ROAD SUITE 800 ATLANTA, GA 30339				
EXAMINER ERIZO, DARWIN P				
ART UNIT		PAPER NUMBER		
3773				
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03/07/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/598,439

Applicant(s)

KOEPEL ET AL.

Examiner

Darwin P. Erez

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 19-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date 12/5/06
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16 and 19-25, drawn to lancing device.

Group II, claim(s) 17 and 18, drawn to a method of collecting a sample of fluid.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group II does not include the special technical features of Group I, such as the drive mechanism.

3. During a telephone conversation with Bradley Groff on 2/28/08 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-16 and 19-25. Affirmation of this election must be made by applicant in replying to this Office action. Claim 17 and 18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 12/5/06 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

Drawings

7. The drawings filed on 8/30/06 are acceptable.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 4, 6, 8-10, 19-22, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,065,871 to Reno.

(claim 1) Reno discloses a lancing device comprising: a housing **12**; a lancet holder **84** for a holding a lancet **82** and mounted for back and forth movement along a lancing stroke path within the housing; and a drive mechanism comprising a pair of off-axis springs (**100** and **96**) coupled to the lancet holder, each of the at least one pair of off-axis springs being positioned laterally offset from the lancing stroke path of the lancet holder (see Figs. 2-7).

(claim 3) There is a trigger **32** to trigger the lancing stroke.

(claim 4) The lancet holder is barbed or held by the lip **108** of the trigger to hold the lancet holder in a ready position, ready for triggering.

(claim 6) The pair of off-axis springs comprises a first torsion spring **96** for advancing the lancet holder along the lancing stroke and an a second torsion spring **100** for retracting the lancet holder.

(claim 8) As stated in claims 1 and 6, Reno discloses a housing **12**; a drive mechanism comprising a carrier **84** for holding the lancet **82**; a first torsion spring **96** for urging the lancet into a piercing position; and a second torsion spring **100** for retracting the lancet holder.

(claim 9) See the rejection to claim 3.

(claim 10) See the rejection to claim 1.

(claims 19-22, 24-25) Reno discloses a reciprocating lancet carrier **84** traversing a linear path to urge a lancet to a piercing position, and a pair of offset torsion springs, as cited in the rejections to claims 1 and 8, and wherein the lancet carrier has a guide cam followers **90,92,94** which are engaged with the torsion springs via the lancet carrier.

10. Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,628,939 to Intengan et al.

(claim 12) Intengan discloses a lancing device comprising: a compact, non-elongated housing **11**; a drive mechanism **27** for movably supporting a lancet **28** along a lancing stroke; a trigger **24** for triggering the drive mechanism; and wherein the housing has a length of no more than about four times as long as the length of the lancet used therein (see Fig. 5).

- (claim 13) The housing is about twice as long as the lancet (width shown in Fig. 5).
- (claim 14) The housing has a width roughly equal to its length (Fig. 5).
- (claim 15) The housing is puck-like.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reno, as applied to the rejections to claim 1, and in view of Intengan ('939).

Reno discloses all the limitations of the claim except for the housing having with comparable to the length of the housing. However, Intengan shows that it is well known in the art for lancing devices to have a housing with a width comparable to a length of the housing. Therefore, it would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to modify the housing of

Reno to have a substantially square side profile because such shape is disclosed as being well known in the art by Intengan. Furthermore, it would also be obvious to modify the shape since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

14. Claims 4, 5 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reno, as applied to the rejections to claim 1, and in view of US 6,190,398 to Schraga.

Reno discloses all the limitation of the claim except for the lancet holder having compressions arm, each having at least one barb, and wherein the trigger engages the barbs. However, Schraga discloses a lancet holder having compressions arm, each having at least one barb, and wherein the trigger engages the barbs (see Fig. 2). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Reno to include the recited arrangement of the lancet holder because simple substitution of one known actuation mechanism for another will obtain predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

15. Claims 7 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reno, as applied to the rejections to claims 1 and 8.

Reno discloses all the limitations of the claims, as applied to the rejections to claims 1 and 8 above, except for the housing being twice as long as the lancet used. However, it would be obvious to one of ordinary skill in the art at the time the invention

was made to modify the housing of Reno to have a length to be twice as long as the lancet since it has been held that such a modification would have involved a mere change in the size of the component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955).

Furthermore, it would have been an obvious to one of ordinary skill in the art at the time the invention was made to modify the housing of Reno to have a substantially square side profile or to have a puck like appearance shape it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezol/
Primary Examiner, Art Unit 3773